UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,723	06/24/2003	Mogens Wumpelmann	10339.200-US	3277

25908 7590 01/24/2005

NOVOZYMES NORTH AMERICA, INC.
500 FIFTH AVENUE
SUITE 1600
NEW YORK, NY 10110

EXAMINER	
KOSSON, ROSANNE	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/603,723	WUMPELMANN ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *8 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 10-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The response to the requirement for election of species filed on December 22, 2004 has been received. Applicants' election of the species of a non-destructive protease (claim 2), a bacterium (claim 4) and plant protein (claim 6) is acknowledged.

Claims 8 and 9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-7 and 10-14 are examined on the merits herewith.

Priority

Applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(a)-(d) or 120 as follows.

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Applicants claim priority to two Danish applications, PA 2002 01021, filed on July 1, 2002, and PA 2002 01838, filed on November 28, 2002, certified copies of which have been received. Applicants also claim priority to two U.S. provisional applications,

60/393,275, filed on July 1, 2002, and 60/430,419, filed on December 2, 2002. The applications filed on November 28 and December 2, 2002 disclose the same invention as the instant application and entitle Applicants to a priority date of November 28, 2002. The applications filed on July 1, 2002 disclose a different invention, namely, a method of improving the yield of a recombinant peptide produced in fermentation by adding monopropylene glycol to the medium. Accordingly, Applicants are not entitled to a priority date of July 1, 2002.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 6, 7 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Huchette et al. (US 4,766,070). Huchette discloses a fermentation method for producing a neutral protease from *Bacillus subtilis* in which the medium contains potato protein as a nitrogen source. Before addition to the medium, the potato protein is prehydrolyzed by treatment with acid and then sterilized by heating to 90 – 110 °C for 5 to 15 minutes. Huchette discloses that this pretreatment of the nitrogen source allows for easier sterilization of the fermentation medium and easier purification of the wort. The pre-treated potato protein represents more than 70% of the nitrogen present on a dry matter basis and about 72-95% of the protein present. See col. 1,

lines 33-41; col. 2, lines 13-25; col. 3, lines 3-14 and 35-40; and Example 3 in cols. 6 and 7). Thus, a holding of anticipation is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huchette et al. (US 4,766,070). As discussed above, Huchette discloses a fermentation method for producing a neutral protease from *Bacillus subtilis* in which the medium contains potato protein as a nitrogen source. Before addition to the medium, the potato protein is prehydrolyzed by treatment with acid and then sterilized by heating to 90 – 110 °C for 5 to 15 minutes. Huchette discloses that this pretreatment of the

nitrogen source allows for easier sterilization of the fermentation medium and easier purification of the wort. The pre-treated potato protein represents more than 70% of the nitrogen present on a dry matter basis and about 72-95% of the protein present. See col. 1, lines 33-41; col. 2, lines 13-25; col. 3, lines 3-14 and 35-40; and Example 3 in cols. 6 and 7). Huchette does not disclose a fermentation in which a self-destructive protease is produced, a fermentation of at least 50 liters or a fermentation that is a repeated batch, fed batch, repeated fed batch or a continuous process. Huchette also does not disclose a prehydrolysis in which 10-70% or 1-20% of the peptide bonds are broken.

Nevertheless, fermentation volume and mode of operation are result-effective parameters which were well known in the art at the time of Applicants' invention to be routinely optimized by one of ordinary skill in the art of bacterial fermentations. Thus, the claimed variations in Applicants' process with respect to these parameters clearly would have been obvious at the time of Applicants' invention, the optimization of these parameters being well within the capabilities of the artisan of ordinary skill at the time of Applicants' invention. Further, the skilled artisan would have recognized that the claimed method would have been carried out in a 50 liter volume or in fed batch, continuous, repeated batch or repeated fed batch with a reasonable degree of success-i.e., medium would have been harvested and fresh medium pumped in as desired. Nothing in the disclosure of Huchette limits the method to batch operation. Also, the skilled artisan would have reasonably expected that a 20 liter fermentation would have been successfully scaled up to a volume of 50 liters or more.

Regarding production of a self-destructive protease, the specification defines a self-destructive protease as one that loses 10% or more of its activity when incubated for 24 hours at the pH and temperature used in the fermentation. One of ordinary skill in the art would have recognized that the method of Huchette is suitable for producing a self-destructive protease, because the skilled artisan would have recognized that the protease, a heat-labile molecule to some degree, at the end of the fermentation, would have been stored at a colder temperature (or separated from the fermentation broth and stored at a colder temperature) and not left to incubate in the fermentation broth at the growth temperature. Post-fermentation handling of the protease does not affect the suitability of the fermentation method disclosed by Huchette for producing a protease.

With respect to the percentage of peptide bonds broken in the hydrolysis step, although Huchette does not disclose a percentage, the reference discloses that acid hydrolysis occurs by contacting the potato protein with an amount of an inorganic or organic acid that lowers the pH to 4.6 to 5.2. One of ordinary skill in the art would have reasonably expected that somewhere between 1% and 70% of the peptide bonds would have been hydrolyzed by this treatment. The skilled artisan would also have recognized that degree of hydrolysis is a result-effective parameter which was well known in the art at the time of Applicants' invention to be routinely optimized by one of ordinary skill in the art of bacterial fermentation, i.e., the degree of hydrolysis would have been increased by using a stronger acid or a higher concentration of the selected acid, and visa versa. Thus, the claimed variations in Applicants' process with respect to this parameters clearly would have been obvious at the time of Applicants' invention, the

optimization of this parameters being well within the capabilities of the artisan of ordinary skill at the time of Applicants' invention.

Thus, a holding of obviousness is required.

No claim is allowed.

The following reference is cited to show further the state of the art: Novozymes A/S, "How to process potatoes without waste," BioTimes, The Enzyme E-zine, September 1, 2000. See, in particular, p. 2 of the article.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner
Art Unit 1651

rk
2005-01-14

FRANCISCO PRATS
PRIMARY EXAMINER